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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/017,621	12/07/2001	Susan M. Freier	RTS-0350	6422

7590

12/08/2004

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EXAMINER

SCHULTZ, JAMES

ART UNIT

PAPER NUMBER

1635

DATE MAILED: 12/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/017,621

Applicant(s)

FREIER ET AL.

Examiner

J. D. Schultz, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 October 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 4-20 is/are pending in the application.
- 4a) Of the above claim(s) 15-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 4-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Status of Application/Amendment/Claims

Applicant's response filed October 1, 2004 has been considered. Rejections and/or objections not reiterated from the previous office action mailed July 1, 2004 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restrictions

Claims 15-20 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on April 21, 2004.

Response to Claim Rejections - 35 USC § 103

Claims 1, 2, and 4-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Okuda *et al.*, in view of Charrasse *et al.*, Taylor *et al.*, and Baracchini *et al.*, and is repeated for the same reasons of record as cited in the Official action mailed July 1, 2004

Applicants traverse the instant rejection by arguing that when viewed alone, none of Okuda *et al.*, Charrasse *et al.*, Taylor *et al.*, or Baracchini *et al.*, teach or suggest modified antisense compounds targeted to the specific regions of the PCTAIRE protein kinase 1 transcript

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of SEQ ID NO: 3 as presently claimed. This argument is not adopted. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). It is acknowledged that the references when viewed individually do not teach the presently claimed invention; however, the test for obviousness is what the *combined* teaching of the prior art would have suggested to those of ordinary skill in the art.

Applicants argue that the primary reference cited, Okuda et al (1992), discloses only the discovery of the PCTAIREI gene and its sequence, and does not teach or suggest the making of antisense compounds targeted to PCTAIREI. However, Okuda was not relied upon for such a teaching. Charrasse, Baracchini, and Taylor et al. were relied upon to teach the motivation to use antisense inhibition and a reasonable expectation of success in accomplishing such methods.

Applicants argue that the secondary references cited fail to overcome the deficiencies in teaching of Okuda, because Charrasse et al. disclose the potential role of this gene in cell cycle-dependent activity, and further assert that nowhere does this paper teach or suggest that antisense compounds or methods would be useful for modulating or inhibited PCTAIREI activity. However, Charrasse et al. was only relied upon to teach motivation to inhibit the expression of PCTAIRE1, because of its implicated role in cell cycle activity, which is a process that goes awry during cancer. Charrasse also teaches inhibition of PCTAIRE1 via expression of a dominant negative mutant, underscoring the desirability of developing inhibitors of this target. Because this paper was not relied upon to teach antisense inhibition all by itself, applicants

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assertion that the reference does not stand alone is not considered germane to the instant rejection.

Applicants also argue that although Taylor et al. is a review paper on the technology of antisense, and that the paper suggests that screening 3-6 oligomers per target is sufficient to find one that inhibits the gene with 66-95% efficiency, this paper does not provide any assurance that a specific gene, such as PCTAIRE1 could be targeted successfully with antisense compounds as claimed. This is not convincing because both Taylor et al. and Baracchini were relied upon to demonstrate a reasonable expectation of success in inhibiting the instant target, because Taylor et al. teaches that any gene can be inhibited provided the gene is known, and because Baracchini et al. teach all that one of ordinary skill would need to know to inhibit a desired target, such as all reagents and active steps, including specific concentrations, precise incubation times, equipment manufacturers, and finally demonstrates how to put these elements together to screen for antisense activity.

Although applicants correctly assert that Baracchini et al. disclose antisense compounds to an entirely different gene, applicants concede that this patent provides teaching of the general technology of antisense. It is maintained that the level of specificity of the disclosure of Baracchini is sufficient to arm one of ordinary skill with the requisite knowledge to make and use antisense oligos to any target, including that of PCTAIRE1 of SEQ ID NO: 3.

As indicated above, one of ordinary skill in the art would have been motivated to make antisense oligonucleotides targeting PCTAIRE1 because Charrasse teach that PCTAIRE1 is a member of the cyclin dependent kinase subfamily, and is highly expressed in post-mitotic tissue. Furthermore, Charrasse *et al.* suggest that this protein may be involved in not only the regulation

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of cellular proliferation, but also may control the state of differentiation. Charrase finally teaches a PCTAIRE-null mutant protein that eliminates PCTAIRE 1 activity, indicating the desirability of studying this protein via mechanisms of inhibition. Moreover, because Baracchini et al. and Taylor et al. teach that synthesizing and using antisense oligos to inhibit transcripts of known sequence is routine to one of ordinary skill in the art, this combination also provides a reasonable expectation of success which render the invention of the claims above obvious under 35 U.S.C. § 103(a). Accordingly, the rejection is maintained.

Conclusion

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Douglas Schultz, Ph.D. whose telephone number is 571-272-0763. The examiner can normally be reached on 8:00-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on 571-272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

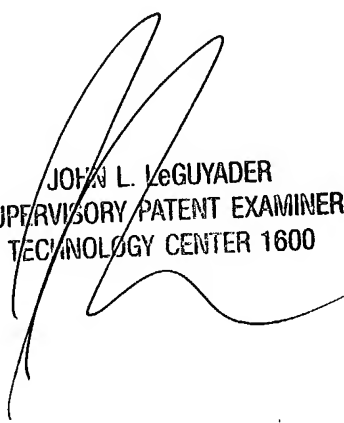
Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service

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center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

JD Schultz, PhD



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